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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,928	VENKATARAMAN, BALAJI	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12,15-19,22-31 and 33-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12,15-19,22-31 and 33-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/26/05.

The amendment filed 09/26/05 affects the application, 10/635,928 as follows:

1. Claims 35-37 have been amended. Claims 6, 13, 14, 20, 21, 32 have been canceled. New Claims 44-47 have been added. This leaves claims 1-5, 7-12, 15-19, 22-31, 33-47.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-5, 7-12, 15-19, 22-31, 33-47 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-19, 22, 24, 30, 33 and 41-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "a condition associated with a hormonal change" in claims 15, 24 and 41-46, renders the claim indefinite. This phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what condition (s) are associated with a hormonal change and how must this or these condition be related to the hormonal change to be considered as being associated with the said hormonal change.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 23, 25-29, 31, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxycobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1).

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1. However, it is common in the art and well within the purview of a skilled artisan to alter formulations such as the vitamin composition of Paradissis et al. by removing components such as vitamin B1 from said composition based on factors such as the medical history, medical health and the daily

medications been taken by the individuals to which the vitamin composition is to be administered. For example, it should be noted that vitamin B1 has side effects such as Allergic reactions including itching or hives, swelling in your face or hand, swelling or tingling in your mouth or throat, chest tightness, trouble breathing, or rash and it is well known that vitamin B1 should not be taken at the same time as the antibiotic tetracycline because it interferes with the absorption and effectiveness of this medication. Vitamin B1 either alone or in combination with other B vitamins should be taken at different times from tetracycline.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 depending on factors such as the medical history, medical health and the daily medications been taken by the individuals to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 depending on factors such as the medical history, medical health and the daily medications been taken by the individuals to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations

consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

In claim 35, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin C." In claim 36, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and iron." In claim 37, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6, vitamin C and iron." Dependent claims 38-40 are drawn to said composition wherein vitamins B12 is hydroxocobalamin.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1).

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition contains vitamin C or iron instead vitamin B1. However, it is common in the art and well within the purview of a skilled artisan to alter formulations such as the vitamin composition of Paradissis et al. by replacing components or ingredients such as vitamin B1 with other well-known vitamin(s) such as vitamin C or mineral (s)such as iron, based on factors such as the medical history, medical health and the daily medications been taken by the individuals to which the vitamin composition is to be administered and the supplemental nutritional needs of the individual. For example, it should be noted that vitamin B1 has side effects such as Allergic reactions including itching or hives, swelling in your face or hand, swelling or tingling in your mouth or throat, chest tightness, trouble breathing, or rash and it is well known that vitamin B1 should not be taken at the same time as the antibiotic tetracycline because it interferes with the absorption and effectiveness of

this medication. Vitamin B1 either alone or in combination with other B vitamins should be taken at different times from tetracycline. The preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan. Furthermore, Paradissis et al. also disclose the use of vitamin C and iron in some of their compositions (example, see col. 10, Example, lines 25-56).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) by replacing components or ingredients such as vitamin B1 with other well-known vitamin(s) such as vitamin C or mineral(s) such as iron, based on factors such as the medical history, medical health and the daily medications been taken by the individuals to which the vitamin composition is to be administered and the supplemental nutritional needs of the individual.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) by replacing components or ingredients such as vitamin B1 with other well-known vitamin(s) such as vitamin C or mineral(s) such as iron, based on factors such as the medical history, medical health and the daily medications been taken by the individuals to which the vitamin composition is to be administered and the supplemental nutritional needs of the individual. It should be noted that the use of different the amounts or quantities of the components in the composition depends on factor like the severity of the condition and the mass or age of individual being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations

consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 15-19, 22, 24, 30, 33, 41-45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson (US 6,040,333).

In claim 15, applicant claims "A method of treating a condition associated with a hormonal change in an individual comprising administering to the individual an effective amount of a vitamin composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 22 is drawn to the method of claim 15, wherein the hormonal change is caused by specific conditions. Claim 46 is drawn to the method of claim 15, wherein the condition with the hormonal change are specific conditions. Claims 24, 30, 33, 41-45, 47 are drawn to a method of treating a condition associated with said hormonal change using specific amounts or quantities of the components in the composition

Jackson discloses a method of treating a condition associated with a hormonal change (menopause) in an individual comprising administering to the individual an effective amount of a vitamin composition comprising calcium, vitamin D, folic acid, vitamin B12 (hydrocobalamin) and vitamin B6 (see col. 11, table 1, line 17 to col. 12, line 20 and, example 1, col. 13, lines 43-64).

The difference between applicant's claimed method and the method of Jackson is that Jackson uses additional vitamins in his composition. However, Jackson discloses that vitamin

B12, vitamin B6 and folic acid (which act synergistically to reduce serum homocysteine) are included in each of his life stage specific dietary supplements of this invention and that other components of the dietary supplements of her invention include vitamin D, calcium, magnesium, manganese, copper, zinc, boron and chromium (col. 5, line 56 to col. 5, line 19). This implies that vitamin B12, vitamin B6 and folic acid are important to be used in each composition and that other supplements such as vitamin D and calcium can be also used in the composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use Jackson's method to treating a condition associated with a hormonal change with a composition consisting of the components or ingredients suggest by Jackson, since Jackson disclose that vitamin B12, vitamin B6 and folic acid (which act synergistically to reduce serum homocysteine) are included in each of his life stage specific dietary supplements of this invention and that other components such as vitamin D and calcium can be included in said composition.

One having ordinary skill in the art would have been motivated to use Jackson's method to treating a condition associated with a hormonal change (such as menopause) with a composition consisting of the components or ingredients suggest by Jackson, since Jackson disclose that vitamin B12, vitamin B6 and folic acid (which act synergistically to reduce serum homocysteine) are included in each of the life stage specific dietary supplements of her invention and that other components such as vitamin D and calcium can be included in said composition. It should be noted that the use of specific amounts or quantities of the components in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated. It should also be noted that, the preparation or alteration of different

vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Response to Amendment

Applicant's arguments with respect to claims 1-5, 7-12, 15-19, 22-31, 33-47 have been considered but are moot in view of the new ground(s) of rejection.

The applicant argues that the term a condition associated with a hormonal change are defined in the specification and that conditions associated with hormonal change include but are not limited to, conditions associated with menopause, hormone replacement therapy, ovariectomy/hysterectomy, cancer therapy, hot flashes, bone loss, high-risk, pregnancy, osteoporosis, endometriosis, and uterine fibroids (see specification, page 13 and 14). However, it is unclear what conditions the applicant intends to treat that are associated with menopause, hormone replacement therapy, ovariectomy/hysterectomy, cancer therapy, hot flashes, bone loss, high-risk, pregnancy, osteoporosis, endometriosis, and uterine fibroids, and how the condition to be treated must be related to be considered an associated condition. Furthermore, the term or phrase "condition associated with a hormonal change" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

6/12/06

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

June 9, 2006.